

REMARKS

I. Status of the Claims

Claims 12-23 are pending. Claims 12, 13 and 22 have been amended. No new matter has been added by these amendments, and no estoppels are intended thereby.

II. Rejection under 35 U.S.C. § 112, second paragraph

The Examiner maintains that Claim 13 is confusing in that it lacks internal antecedent basis for "said biomolecules." Claim 13 has been amended in view of the Examiner's arguments and this rejection is moot. The Examiner further states that Claim 13 is vague, indefinite, and confusing in the recitation of "insulins and their analogs." Applicants direct the Examiner to page 3, lines 28 -32, of the specification where non-limiting examples of analogs of insulin are described. By analogs, Applicants mean structurally similar compounds as described in on page 3, lines 28-32. One of ordinary skill in the art would therefore understand what is meant by insulin and their analogs. Further the Examiner maintains that "corresponding precursors" of these analogs are not set forth in the specification. Applicants again direct the Examiner to page 3, lines 22-26, of the specification where corresponding precursors are discussed. The specification further cites preproinsulins as an example of corresponding precursors. See page 4, lines 4-6 of the specification. Based on these disclosures, one of ordinary skill of art thus would not find the terms vague, indefinite, or confusing. Thus, Applicants traverse this rejection.

The Examiner maintains that claims 12 and 13 are vague, indefinite, and confusing in the recitation of "substantially no pores." The M.P.E.P. specifically

teaches that "the term 'substantially' is often used in conjunction with another term to describe a particular characteristic of the claimed invention. M.P.E.P. § 2173.05(b). Here, Applicants use the word "substantially" in conjunction with the phrase "no pores." Further, under M.P.E.P. § 2173.02, "definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level in the pertinent art at the time the invention was made. Based on the disclosures in the specification, one of ordinary skill of art would not find the term "substantially" vague, indefinite, or confusing. Applicants again respectfully direct the Examiner to page 3, lines 9-21, of the specification in which "substantially no pores" is defined as meaning "no or almost no pores which are large enough that the enzymes can bind to the support within these pores." Thus, the phrase "substantially no pores" is definite as used in the general guidelines of the specification. See *In re Mattison*, 509 F.2d 563 (CCPA 1975); M.P.E.P. § 2173.05(b). Nonetheless, Applicants have amended the claims in this application to remove the "substantially no pores" language. Thus, Applicants respectfully request that this rejection be reversed.

In light of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

III. Claim Rejections under 35 U.S.C. § 102(b)

Claim 12 is rejected under 35 U.S.C. § 102(b) as being anticipated by *Lorenzen et al.* for reasons set forth on page 3 of the Office Action.

Claim 12 is drawn to a process for enzymatic extraction of biomolecules. The Examiner maintains *Lorenzen et al.* teaches enzymatic extraction of phosphopeptides

from casein using "a polymeric support material which has no pores or substantially no pores, such as oxirane acrylic beads using trypsin." The *Lorenzen* reference discloses that the polymeric support is oxirane beads which go by the tradename Eupergit C. In addition, Applicants have amended claim 12 to be directed to a material with no pores. Applicants teach, however, that Eupergit C is not a pore free support and the use of this support did not achieve the benefits of the invention when used by Applicants and instead resulted in an unsatisfactory reaction pattern." See page 2, line 24 of the specification; page 4, lines 15-24 of the specification; *Lorenzen*, page 119. This teaching is supported by the technical sheet from Röhm Pharma Polymers enclosed, which demonstrates that Eupergit C and Eupergit C 250 L are both porous. By comparison, Eupergit C1Z, a pore free support, was used and did achieve the benefits of the invention. See page 4, lines 25-36, of the specification. Indeed, Applicants describe Eupergit C1Z as a pore free support which allowed "for the first time" one to achieve the benefits of the invention. See page 4, lines 29-31, of the specification. Accordingly, the *Lorenzen* reference does not disclose every aspect of Claim 12 either explicitly or impliedly. For at least this reason, Applicants respectfully request withdrawal of this rejection. *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); see also M.P.E.P. 706.02(a) ("[f]or anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly").

IV. Rejection under 35 U.S.C. § 103(a)

Claims 12-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Jakubke et al.* taken with *Lorenzen et al.*, *Eckstein*, *Huwig et al.*, and *Hillegas et al.*

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To establish a *prima facie* case of obviousness, the Examiner must demonstrate that there is some suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the teachings of a reference or combine the teachings of the references. See M.P.E.P. § 2143. In the present case, the above criteria have not been established.

The references cited by the Examiner, *Jakubke, Lorenzen, Eckstein* and *Huwig*, do not teach processes for enzymatic extraction of biomolecules as discussed at pages 5-7 of Applicants Amendment Under 37 C.F.R. § 111 of October 16, 2002. Applicants note that the Examiner has presented no evidence that the Eupergits cited (*i.e.*, Eupergit C and Eupergit C250L) do not contain pores. In fact, contrary evidence is submitted herewith that shows Eupergit C does contain pores. See *Rohm Pharma Polymers* reference. Applicants teach that the Eupergit C and C250L fail to achieve the benefits of the claimed invention.

In comparison, Applicants specifically teach that Eupergit C1Z, a pore free material, achieved the advantages of the invention "for the first time" whereas the supports identified by the examiner are described as conventional supports, *i.e.*, they are not pore free or substantially pore free. See page 2, lines 20-27 of the specification. Thus, there is no teaching in any of the cited references to enzymatically extract biomolecules from supports that are free of or substantially free of pores.

The Examiner states that Applicants' examples are only directed to the production of insulin from preproinsulin at specific process conditions while the claim 12 is broadly directed to the production of peptides, proteins, oligosaccharides, and polysaccharides with unidentified enzymes and claim 13 is directed to extracting

insulins and producing "biomolecules" with unidentified enzymes. Applicants, however, are not limited to claiming a specific example. Rather "there is no doubt that a patentee's invention may be broader than the particular embodiment shown in a specification. A patentee is entitled not only to narrow claims particularly directed to the preferred embodiment but also to broad claims which define the invention without a reference to specific instrumentalities." *Application of Anderson*, 471 F.2d 1237, 1241 (CCPA, 1973). Accordingly, claims 12 and 13 are entirely proper and fully supported by the examples and the remainder of the specification.

For these reasons, the Examiner is request to reconsider and withdraw this §103(a) rejection.

IV. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration of the pending claims and reexamination of the application. The amendments to the claims is made in compliance with 37 C.F.R. § 1.116, and particularly 37 C.F.R. § 1.116(b), which states that "[a]mendments presenting rejected claims in better form for consideration on appeal may be admitted." No new matter has been added by the proposed amendments nor does the amendments raise new issues or necessitate the undertaking of any additional search of the art by the Examiner. All of the elements and their relationships now claimed were earlier claimed in the claims as examined. Therefore, this Amendment under 37 C.F.R. § 1.116 should allow for immediate action by the Office. Moreover, as this amendment is responsive to the Examiner's rejection that claims 12 and 13 were indefinite based on the recitation of "substantially no pores" and to correct a typographical error in claim 22, this amendment

is made to place the claims in a position for allowance, or at least in a better form for appeal if necessary, and Applicants respectfully request that the claims be allowed.

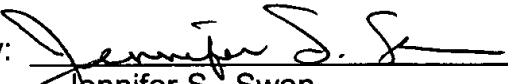
Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0196.

Respectfully submitted,

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Appendix-Amended Claims

- 12. (Amended) A process for enzymatic extraction of biomolecules, comprising:
- providing a polymeric support comprising one [of] or more enzymes bonded thereto, wherein the polymeric support material has no pores or [substantially no pores];
 - extracting said biomolecules from the group consisting of peptides, proteins, oligosaccharides, and polysaccharides; and
 - obtaining said biomolecules.
- 13. (Amended) A process for extraction, comprising:
- providing a polymeric support comprising one or more enzymes bonded thereto, wherein the polymeric support material has no pores or [substantially no pores];
 - extracting insulins or their analogs from corresponding precursors; and
 - obtaining [said] biomolecules.
- 22. (Amended) The process as in claim 13, wherein said enzyme polymeric support material is a copolymer of the monomers [methacryamide] methacrylamide and N, N'-bis(methacrylamide).--